

**Food and Drug Administration, HHS**

**§ 892.1700**

**§ 892.1620 Cine or spot fluorographic x-ray camera.**

(a) *Identification.* A cine or spot fluorographic x-ray camera is a device intended to photograph diagnostic images produced by x-rays with an image intensifier.

(b) *Classification.* Class II.

**§ 892.1630 Electrostatic x-ray imaging system.**

(a) *Identification.* An electrostatic x-ray imaging system is a device intended for medical purposes that uses an electrostatic field across a semiconductive plate, a gas-filled chamber, or other similar device to convert a pattern of x-radiation into an electrostatic image and, subsequently, into a visible image. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

**§ 892.1640 Radiographic film marking system.**

(a) *Identification.* A radiographic film marking system is a device intended for medical purposes to add identification and other information onto radiographic film by means of exposure to visible light.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 892.9.

[55 FR 48444, Nov. 20, 1990, as amended at 59 FR 63015, Dec. 7, 1994; 66 FR 38819, July 25, 2001]

**§ 892.1650 Image-intensified fluoroscopic x-ray system.**

(a) *Identification.* An image-intensified fluoroscopic x-ray system is a device intended to visualize anatomical structures by converting a pattern of x-radiation into a visible image through electronic amplification. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II. When intended as an accessory to the device described in paragraph (a) of this section, the fluoroscopic compression de-

vice is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 892.9.

[53 FR 1567, Jan. 20, 1988, as amended at 66 FR 57369, Nov. 15, 2001]

**§ 892.1660 Non-image-intensified fluoroscopic x-ray system.**

(a) *Identification.* A non-image-intensified fluoroscopic x-ray system is a device intended to be used to visualize anatomical structures by using a fluorescent screen to convert a pattern of x-radiation into a visible image. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

**§ 892.1670 Spot-film device.**

(a) *Identification.* A spot-film device is an electromechanical component of a fluoroscopic x-ray system that is intended to be used for medical purposes to position a radiographic film cassette to obtain radiographs during fluoroscopy.

(b) *Classification.* Class II.

**§ 892.1680 Stationary x-ray system.**

(a) *Identification.* A stationary x-ray system is a permanently installed diagnostic system intended to generate and control x-rays for examination of various anatomical regions. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

**§ 892.1700 Diagnostic x-ray high voltage generator.**

(a) *Identification.* A diagnostic x-ray high voltage generator is a device that is intended to supply and control the electrical energy applied to a diagnostic x-ray tube for medical purposes. This generic type of device may include a converter that changes alternating current to direct current, filament transformers for the x-ray tube, high voltage switches, electrical protective devices, or other appropriate elements.

(b) *Classification.* Class I (general controls). The device is exempt from the

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premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 892.9.

[53 FR 1567, Jan. 20, 1988, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38819, July 25, 2001]

### § 892.1710 Mammographic x-ray system.

(a) *Identification.* A mammographic x-ray system is a device intended to be used to produce radiographs of the breast. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

### § 892.1715 Full-field digital mammography system.

(a) *Identification.* A full-field digital mammography system is a device intended to produce planar digital x-ray images of the entire breast. This generic type of device may include digital mammography acquisition software, full-field digital image receptor, acquisition workstation, automatic exposure control, image processing and reconstruction programs, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II (special controls). The special control for the device is FDA's guidance document entitled "Class II Special Controls Guidance Document: Full-Field Digital Mammography System." See § 892.1(e) for the availability of this guidance document.

[75 FR 68203, Nov. 5, 2010]

### § 892.1720 Mobile x-ray system.

(a) *Identification.* A mobile x-ray system is a transportable device system intended to be used to generate and control x-ray for diagnostic procedures. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

### § 892.1730 Photofluorographic x-ray system.

(a) *Identification.* A photofluorographic x-ray system is a

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device that includes a fluoroscopic x-ray unit and a camera intended to be used to produce, then photograph, a fluoroscopic image of the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

### § 892.1740 Tomographic x-ray system.

(a) *Identification.* A tomographic x-ray system is an x-ray device intended to be used to produce radiologic images of a specific cross-sectional plane of the body by blurring or eliminating detail from other planes. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

### § 892.1750 Computed tomography x-ray system.

(a) *Identification.* A computed tomography x-ray system is a diagnostic x-ray system intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from the same axial plane taken at different angles. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

### § 892.1760 Diagnostic x-ray tube housing assembly.

(a) *Identification.* A diagnostic x-ray tube housing assembly is an x-ray generating tube encased in a radiation-shielded housing that is intended for diagnostic purposes. This generic type of device may include high voltage and filament transformers or other appropriate components.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 892.9.

[53 FR 1567, Jan. 20, 1988, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38819, July 25, 2001]